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| APPLICATION NO.  | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO.         | CONFIRMATION NO.       |
|--|-------------|----------------------|-----------------------------|------------------------|
| 10/785,449   | 02/24/2004  | Tracee Eidenschink   | S63.2-111487                | 8514                   |
| 23552  | 7590        | 06/19/2007           |                             |                        |
| MERCHANT & GOULD PC<br>P.O. BOX 2903<br>MINNEAPOLIS, MN 55402-0903 |             |                      | EXAMINER<br>KOTINI, PAVITRA |                        |
|  |             |                      | ART UNIT<br>3731            | PAPER NUMBER           |
|  |             |                      | MAIL DATE<br>06/19/2007     | DELIVERY MODE<br>PAPER |

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

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|                              |                                      |  |  |
|------------------------------|--------------------------------------|--|--|
| <b>Office Action Summary</b> | <b>Application No.</b><br>10/785,449 | <b>Applicant(s)</b><br>EIDENSCHINK, TRACEE |  |
|                              | <b>Examiner</b><br>Pavitra Kotini    | <b>Art Unit</b><br>3731                    |  |

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 08 May 2007.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-50 is/are pending in the application.
- 4a) Of the above claim(s) 49 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-48, 50 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date <u>3/22/04</u> . | 6) <input type="checkbox"/> Other: _____  |

## **DETAILED ACTION**

### ***Election/Restrictions***

Applicant's election of Group I in the reply filed on 5/8/07 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)). Claim 49 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

**Claims 1-48 and 50** are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention. Specifically it is unclear how the balloon is secured on the catheter shaft without sliding off when the collars are in the non-activated state. In claim 1, it is stated that the balloon is rotatable about the proximal and distal waist and in the activated state they engage the collars. This would imply that there is no association between the

collars and waits in the non-activated state. So, how does the balloon remain on the catheter if it is not in connection with any part of the catheter?

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 1, 19, 28-33, 35-40, and 50** are rejected under 35 U.S.C. 102(e) as being anticipated by Gumm (US-20030055483).

Gumm discloses a catheter assembly comprising:

Regarding **claims 1 and 50** a catheter shaft (14), the catheter shaft having a length and an outer surface; a balloon (28), the balloon comprising a proximal balloon waist(30), a distal balloon waist (32) and a body portion (28) there between, the balloon having an expanded state and a unexpanded state, in the expanded state the body portion having an expanded diameter and in the unexpanded state the body portion having an unexpanded diameter that is less than the expanded diameter (inherent); and a proximal collar (24) and a distal collar (26), the proximal collar engaged to the catheter shaft and the distal collar engaged to the catheter shaft (para.0040), each collar having a nonactivated state and an activated state, in the nonactivated state the distal balloon

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waist being rotatable about the distal collar and the proximal balloon waist being rotatable about the proximal collar (para.0041), in the activated state the proximal collar being expanded to sealingly engage the proximal balloon waist and the distal collar being expanded to sealingly engage the distal balloon collar (para.0041, 0045).

Regarding **claims 19 and 31**, it is old and well known in the art for the balloon and the secondary guidewire housing to be constructed of at least one member of the group consisting of: Pebax, Nylon, PET, polyester, polyolefin copolymer and any combination thereof. See for example, US patent #s 4838859, 4906244, 4950239, 5290306, and 2002/0146557.

Regarding **claim 28**, a distal hub (22), the distal hub fixedly engaged to the catheter shaft distal of the distal collar.

Regarding **claim 29**, a proximal hub (20), the proximal hub fixedly engaged to the catheter shaft proximal of the proximal collar.

Regarding **claim 30**, a secondary guidewire housing (60), the secondary guidewire housing comprising a substantially tubular member engaged to the balloon (fig. 2), the secondary guidewire housing defining a secondary guidewire lumen through which a secondary guidewire (62) may be slidingly positioned.

Regarding **claims 32, 33, and 35**, figure 4 discloses the secondary housing guidewire integral and engaged to the balloon and extending from a proximal end to an intermediate region of the balloon.

Regarding **claim 36**, the secondary guidewire (62) has a length at least as long as the balloon body (fig. 2)

Regarding **claim 37**, a balloon expandable stent (50), the stent being expandable from an unexpanded configuration to an expanded configuration, in the unexpanded configuration the stent being disposed about at least a portion of the balloon body (para.0043).

Regarding **claim 38**, at least a proximal portion of the stent (50) overlays at least a portion of the secondary guidewire housing (fig. 2).

Regarding **claim 39**, the stent (50) comprises a plurality of interconnected members, wherein adjacent members define openings there between, one of the openings being a secondary opening (64) through which the secondary guidewire (62) radially extends (fig. 2).

Regarding **claim 40**, a distal end of the secondary guidewire housing (60) extends radially through the secondary opening (64).

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

**Claims 16-18** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Gerberding et al. (US-6315790).

Gumm discloses the invention substantially as disclosed above, but fails to disclose marker bands.

Gerberding teaches marker bands (30), wherein at least one marker band is at least partially radiopaque and are detectable by X-ray (col.4, line 9-11).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the catheter disclosed by Gumm to include marker bands as taught by Gerberding.

**Claim 34** is rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Marton (US-2001/0032013).

Gumm discloses the invention substantially as claimed, but fails to disclose welding the secondary guidewire lumen to the balloon.

However, Marton teaches welding as a means to attach two components such as tubes together. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the secondary guidewire lumen disclosed by Gumm to be attached by welding as taught by Marton. Such a modification would ensure the two components are attached together more securely.

**Claims 41, 42, and 46** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Pinchuk et al. (US-2002/0107330).

Gumm discloses the invention substantially as disclosed above, but fails to disclose a polymer or therapeutic coating to the stent.

However, Pinchuk teaches various therapeutic coatings (para.0005) and polymers (para.0016) as coatings on the stent. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stent as

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disclosed by Gumm to include such coatings. Such a modification would enhance local drug delivery and reduce the systemic side effects associated with traditional oral drug delivery.

**Claims 43-45** are rejected under 35 U.S.C. 103(a) as being unpatentable over Gumm (US-20030055483) in view of Pinchuk et al. (US-2002/0107330).

Gumm discloses the invention substantially as disclosed above, but fails to disclose specific genetic coatings on a stent or cells. However, Pinchuk teaches genetic therapeutic coatings (para.0077) such as antisense DNA and RNA or tumor necrosis factor or cells (para.0091) including stem cells. Therefore, it would have been obvious to a person of ordinary skill in the art at the time of the invention to modify the stent as disclosed by Gumm to include a genetic coating as taught by Pinchuk. Such a modification would provide a means for gene delivery.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Pavitra Kotini whose telephone number is 571-272-0624. The examiner can normally be reached on M-F 8:30am to 6:00pm.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

P. Kotini  
AU 3731

  
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PRIMARY EXAMINER  
6/11/07